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Attorney for Applicant(s) — Date of Signature: 22 Nov 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	**DONNA G. ALBERTSON, DANIEL PINKEL, COLIN COLLINS, JOE W. GRAY and BAUKE YSTRA**
Assignee:	**The Regents of the University of California**
Title:	**AMPLIFICATION OF CYP24 AND USES THEREOF**
Serial No.:	**09/285,292** Filing Date: **April 2, 1999**
Examiner:	**A. Harris** Art Unit: **1642**
Docket No.:	**M-8979US**

COMMISSIONER FOR PATENTS
Washington, D. C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

In response to the Office Action dated 19 June 2000, Applicants respectfully request reconsideration of the above-identified application in view of the following amendments and remarks. A change of correspondence address and a petition to extend the period of response for five months is enclosed.

In the Office Action dated 19 June 2000, the Examiner required restriction to one of the following groups under 35 U.S.C. §121:

Group I: Claims 1-8, 13-24, and 28-32 drawn to a method of detecting a predisposition to cancer comprising detecting the level of CYP24 mRNA;

Group II: Claims 1, 9, 10, 13-18, 25, and 28-32 drawn to a method of detecting a predisposition to cancer comprising detecting the level of CYP24 protein;

Group III: Claims 1, 11-18, and 26-32, drawn to a method of detecting a predisposition to cancer comprising detecting the level of 25 hydroxyvitamin D3 24-hydroxylase enzyme;

Group IV: Claims 33-41 and 46-50, drawn to a method of treating cancer comprising detecting CYP24 genes;

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Group V: Claims 33, 42, and 43, drawn to a method of treating cancer involving detecting CYP24 protine;

Group VI: Claims 33, 44, and 45, drawn to a method of treating cancer involving detecting 25 hydroxyvitamin D3 24-hydroxylase activity;

Group VII: Claims 51-54 and 59-70, drawn to a method of screening a test agent comprising detecting the level of CYP24 mRNA;

Group VIII: Claims 51, 55, and 56, drawn to a method of screening a test agent comprising detecting the level of CYP24 protein; and

Group IX: Claims 51, 57, and 58, drawn to a method of screening a test agent comprising detecting 25 hydroxyvitamin D3 24-hydroxylase activity;

In response to this restriction requirement Applicants provisionally elect Group I, claims 1-8, 13-24, and 28-32 with traverse.

Applicants initially note that the restriction between Groups I, II, and III, between Groups IV, V, and VI, and between Groups VII, VIII, and IX is ***legally improper*** because the Examiner effectively requires that a single claim (*i.e.,* claim 1, claim 33, or claim 51) be divided up and presented in several applications. This flatly contravenes accepted law. As stated by the CCPA:

> As a general proposition, an applicant has a right to have ***each claim*** examined on the merits.
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> * * *
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> If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.
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> * * *
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> §121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions, ... It does not provide a basis under the authority of the Commissioner to *reject* a particular *claim* on that same basis.
>
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> We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses. *In Re Weber, Soder and Boksay* 198 USPQ 328, 331-332 (CCPA 1978)

See also, *In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*).

The CCPA thus recognized that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. *See, In re Weber Soder and Boksay, supra.* Moreover the CCPA recognized that imposition of a restriction requirement on a single claim is just such an improper rejection.

In particular, the courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. §121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I, and In Re Haas II.* More specifically, the CCPA expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it. *In Re Weber* at 334.

Applicants recognize that instead of improperly imposing a restriction requirement on a single claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim. *See*, 37 C.F.R. §1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. §112 are complied with. *See, e.g.,* the MPEP at 803.02, *In Re Wolfrum* 179 USPQ 620 (CCPA, 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (CCPA, 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications that are incapable of capturing the intended scope of the application. It should be clear that the added cost of filing and prosecuting nine divisional patent applications in the

present case does not strike an appropriate balance between the administrative concerns of the office and Applicants statutory rights as an inventor.

Finally, Applicants note that the CCPA has explicitly held that improper restriction of a single claim is a decision under the jurisdiction of the Board of Appeals, and the Federal Courts. This is in contrast to simple administrative decisions regarding ordinary restriction requirements, which are not generally subject to Appellate review. See, *In Re Haas I, supra.* Because restriction of a single claim into multiple groups is tantamount to a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the Board of Appeals and the courts have jurisdiction over the decision. Accordingly, Applicants expressly reserve the right to appeal any decision that may be made regarding the present petition to the Patent Office Board of Appeals and to the Federal Circuit.

In view of the foregoing, Applicants have established that the restriction between Groups I, II, and III, between Groups IV, V, and VI, and between Groups VII, VIII, and IX is legally improper and respectfully request that the restriction between these groups be withdrawn.

Applicants also submit that restriction between Groups I-III, IV-VI, and VII-IX is unnecessary. According to MPEP §803, the Examiner should examine all claims in an application, **even though they are directed to distinct inventions**, unless to do so would create a **serious burden**. In the instant case, the claims of Groups I-III are drawn to methods of detecting a predisposition to cancer by detecting CYP24 gene amplifications and transcription products (*e.g.* mRNA, protein) produced by such amplifications. The claims of Groups VI-VI are drawn to methods of treating cancer that involve detecting CYP24 gene amplifications. A search for prior art relevant to detection of CYP24 gene amplifications and/or upregulation will also identify, if it exists, prior art relevant to the detection of CYP24 gene amplifications as an element of a cancer treatment. Thus, a search for prior art relevant to Groups I-III will entail no greater effort than a search for prior art relevant to Groups IV-VI. Thus Examination of Groups I-VI together does not impose a serious burden and these Groups should be reunited.

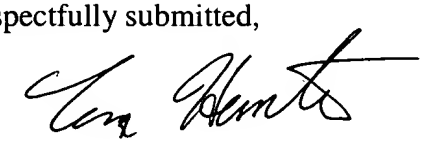
The claims of Groups VII-IX are drawn to method of screening for a test agent that modulates CYP24 activity. Again, a search for prior art relevant to detection of CYP24 gene amplifications and/or upregulation will also identify, if it exists, prior art relevant to the claimed methods of screening for test agents that modulate CYP24 expression. Thus, a search for prior art relevant to Groups VII-IX will entail no greater effort than a search for prior art

relevant to Groups I-VI. Thus, Examination of Groups I-IX together does not impose a serious burden and these Groups should be reunited.

In view of the foregoing, Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (415) 217-6021.

Respectfully submitted,



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Encl: 1) Change of correspondence address.
2) Petition for 5 month extension of time.

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